Complete Summary

GUIDELINE TITLE

Diagnostic laparoscopy in primary and secondary infertility. In: Diagnostic laparoscopy guidelines.

BIBLIOGRAPHIC SOURCE(S)

Diagnostic laparoscopy in primary and secondary infertility. In: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Diagnostic laparoscopy guidelines. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2007 Nov. p. 61-5.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for diagnostic laparoscopy. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2002 Mar. 5 p.

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

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SCOPE

DISEASE/CONDITION(S)

Infertility (primary and secondary)

GUIDELINE CATEGORY

Diagnosis Evaluation

CLINICAL SPECIALTY

Obstetrics and Gynecology Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist surgeons' decisions about the appropriate use of diagnostic laparoscopy in women with infertility
- To update the previous 2002 guidelines on this topic

TARGET POPULATION

Women with primary and secondary infertility, particularly after normal hysterosalpingography

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic laparoscopy in women with infertility

MAJOR OUTCOMES CONSIDERED

- Conversion to open procedure rate
- Procedure-related/intraoperative complications
- Procedure-related morbidity
- Missed intraoperative complication rate
- Pregnancy rate within 1 year
- Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic literature search of MEDLINE for the period 1995-2005 was limited to English language articles. The search strategy is shown in Figure 1 in the original guideline document. Using the same strategy, the Cochrane database of evidence-based reviews and the Database of Abstracts of Reviews of Effects (DARE) were searched.

Abstracts were reviewed by three committee members and into the following categories:

- Randomized studies, meta-analyses, and systematic reviews
- Prospective studies
- Retrospective studies
- Case reports
- Review articles

Randomized controlled trials, meta-analyses, and systematic reviews were selected for further review along with prospective and retrospective studies that included at least 50 patients; studies with smaller samples were reviewed when other available evidence was lacking. The most recent reviews were also included. All case reports, old reviews, and smaller studies were excluded.

The reviewers graded the level of evidence of each article and manually searched the bibliographies for additional articles that may have been missed by the search. Any additional relevant articles were included in the review and grading.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization
	Or
	Cohort of case-control studies
	Or
	Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

To maximize the efficiency of the review, articles were divided into three subject categories:

- Staging laparoscopy for cancer
- Diagnostic laparoscopy for acute conditions
- Diagnostic laparoscopy for chronic conditions

Reviewers graded the level of each article (see "Rating Scheme for the Strength of the Evidence.")

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines were developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and revised by the SAGES Guidelines Committee.

The statements included in this guideline are the product of a systematic review of published work on the topic, and the recommendations are explicitly linked to the supporting evidence. The strengths and weaknesses of the available evidence are described and expert opinion sought where the evidence is lacking. This is an update of previous guidelines on this topic (last revision 2002) as new information has accumulated.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Scale Used for Recommendation Grading

Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel
Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

COST ANALYSIS

The literature was reviewed for published cost analyses. No evidence exists on the cost-effectiveness of diagnostic laparoscopy (DL) for infertility.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations of each guideline undergo multidisciplinary review and are considered valid at the time of production based on the data available. This statement was reviewed by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), November 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of the recommendations (**A, B, C**) and the levels of evidence (**I, II, III**) are provided at the end of the "Major Recommendations" field.

General Recommendations for Diagnostic Laparoscopy

Diagnostic laparoscopy (DL) is a safe and well tolerated procedure that can be performed in an inpatient or outpatient setting under general or occasionally local anesthesia with intravenous sedation in carefully selected patients. Diagnostic laparoscopy should be performed by physicians trained in laparoscopic techniques who can recognize and treat common complications and can perform additional therapeutic procedures when indicated. During the procedure, the patient should be continuously monitored, and resuscitation capability must be immediately available. Laparoscopy must be performed using sterile technique along with meticulous disinfection of the laparoscopic equipment. Overnight observation may be appropriate in some outpatients.

Diagnostic Laparoscopy for Primary and Secondary Infertility

Technique

The lithotomy position is employed so that cervical manipulation can be used. When cervical manipulation is not needed, standard prone positioning is used. A primary trocar site is placed in the periumbilical region, and additional trocars are placed in the right and or left lower quadrants as needed. Methylene blue or other dye can be injected into the fallopian tube to check for patency. Peritoneal fluid can be obtained to check for endometriosis. Endometriosis observed should be biopsied and classified with tools such as the American Society for Reproductive Medicine Guidelines. Adhesions can be identified and classified as mild, moderate, or severe. Pathology affecting the fallopian tube can be classified as mild (a superficial vascular pattern suggesting congestion or inflammation and/or minimal kinking, and/or minimal fibrosis), moderate (salpingitis, isthmica, nodosum, distal phimosis, high degrees of vascular change, fibrosis, ampullary dilation after visualization with chromotubation), or severe (obstruction of the tube proximally or distally). Treatment of identified pathology can be initiated at this time.

Indications

Infertility particularly after normal hysterosalpingography.

Recommendations

Diagnostic laparoscopy (DL) can be used safely in female patients with infertility (**Grade B**). DL may be considered in appropriately selected infertile patients even after normal hysterosalpingograms, as important pelvic pathology may be identified in a significant number of patients (**Grade C**). The paucity of available data and the low level of evidence do not substantiate a firm recommendation for the procedure.

For details of the rationale for the procedure and its diagnostic accuracy, see the original guideline document.

Definitions:

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization
	Or
	Cohort of case-control studies
	Or
	Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

Scale Used for Recommendation Grading

Grade A	Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
Grade B	Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel
Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Identification of the reason for infertility
- Possible therapeutic intervention
- Confirmation of lack of pathology may also be important for further treatment options

POTENTIAL HARMS

Procedure- or anesthesia-related complications (see "Procedure-related Complications and Patient Outcomes" section in the original guideline document)

CONTRAINDICATIONS

CONTRAINDICATIONS

Inability to tolerate general anesthesia or significant pelvic adhesions that may preclude safe access or visualization

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. The approach suggested may not be the only acceptable approach given the complexity of the health care environment. These guidelines are intended to be flexible, as the surgeon must always choose the approach best suited to the patient and variables in existence at the time of the decision.

Limitations of the Available Literature

The quality of the available literature is limited, as all of the available studies are retrospective studies from single institutions. Furthermore, there is a paucity of data on long-term outcomes and pregnancy rates and no data on cost-effectiveness and quality of life. In addition, there is no consistency in the reporting of pregnancy success after laparoscopy, as some studies consider the use of *in vitro* fertilization a success and others a failure. These shortcomings limit the guideline developers' ability to provide firm recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Apr (revised 2007 Nov)

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site</u>.

Print copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

 Patient information for diagnostic laparoscopy from SAGES. Available in English and Polish from the <u>Society of American Gastrointestinal and</u> <u>Endoscopic Surgeons (SAGES) Web site</u>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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